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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,610	09/10/2003	Dale C. Kenison	70021220.0092	5384

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EXAMINER	
GRAY, PHILLIP A	

ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/659,610	KENISON ET AL.	
	Examiner	Art Unit	
	Phillip Gray	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to applicant's communication of 8/23/2006.

Response to Arguments

Applicant's arguments filed 8/23/2006 have been fully considered but they are not persuasive.

Applicant's argues that the examiner provides nothing to support a reasonable expectation of success in combining the cited references, the examiner relied on impermissibly hindsight, and that "numerous other potential pitfalls" loom over combination (no examples were given by applicant).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that the examiner provides nothing to support a reasonable expectation of success in combining the cited references, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed

invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

During examination, claim limitations are to be given their broadest reasonable reading. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); In re Prater, 415 F.2d 1393, 1404-1405, 162 USPQ 541, 550-51 (CCPA 1969). As explained in the rejection below, the elements disclosed in Johnson/Runkel/Wallace are fully capable of satisfying all structural, functional, spatial, and operational limitations in the amended claims, as currently written, and the rejection is made and proper. See rejection discussion below.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the combination of the treatment method (Johnson discloses a method and apparatus for implanting in cattle's ear subcutaneously), the treatment method (Runkel discloses hybrid controlled extended release subcutaneous implants in a bioerodible matrix and binding agents), and the treatment method type (Wallace discloses a fescue toxicosis treatment using ivermectin or a related avermectin compound) and there combination thereof, are all

known in the knowledge generally available to one of ordinary skill in the art. See rejection below.

Claim Rejections - 35 USC § 103 (2nd time)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9-20, 23-24, 26-28, 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (U.S. Patent Number 4,799,921) in view of Runkel et al. (U.S. Patent Number 5,035,891) in further view of Wallace (U.S. Patent Number 4,847,243). Johnson discloses a method and apparatus for implanting in cattle's ear subcutaneously (see Johnson figure 1 and abstract). Runkel discloses hybrid controlled extended release subcutaneous implants in a bioerodible matrix and binding agents, of lactose, cellulose, PEG, magnesium stearate (a disintegration agent), ect. (see paragraphs at columns 1-4). Wallace discloses a fescue toxicosis treatment using ivermectin or a related avermectin compound (see Wallace paragraph at column 1 line 64 through column 2 line 8).

Johnson discloses the claimed invention except for the immediate and extended release ivermectin parasitic agent pellet dose. Runkel teaches that it is known to use controlled release subcutaneous implants in a bioerodible matrix of disintegration aid and binding agents, of lactose, cellulose, PEG, magnesium stearate, ect., (as set forth

in Runkel paragraphs at columns 1-4). Wallace teaches that it is known to use ivermectin or a related avermectin (as set forth in Wallace paragraph at column 1 line 64 through column 2 line 8), to provide a fescue toxicosis treatment for animals.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus for implanting in cattle's ear subcutaneously as taught by Johnson with a controlled extended release subcutaneous implants in a bioerodible matrix of disintegration aid and binding agents, of lactose, cellulose, PEG, magnesium stearate, ect. as taught by Runkel, with ivermectin or a related avermectin as taught by Wallace since such a modification would provide the subcutaneous implant with an ivermectin, or a related avermectin, in a bioerodible matrix of disintegration aid and binding agent for providing an antiparisiticidal agent for treating animals in a controlled extended release dosage.

Claims 21-22, 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (U.S. Patent Number 4,799,921) in view of Runkel et al. (U.S. Patent Number 5,035,891) in further view of Wallace (U.S. Patent Number 4,847,243).

Johnson in view of Runkel discloses a method and device for implanting cattle with a controlled release subcutaneous implant (see above comments). Wallace discloses administering a parasiticidal agent at a rate from 0.004 to 2.0 mg/kg of body weight, which may vary depending upon the particular animal treated (see Wallace paragraphs beginning at column 5, lines 20-57). With full grown cows weighing anywhere from 700-1500 lbs, this could very well be as much as 3000 mg per dosage of parasiticidal agent. Further, Wallace discloses that the extended release delivery period

is of 120 days (see paragraphs beginning at column 5, lines 3 - 57). This discloses the ranges of 25-125 mg of immediate release and 50-175 mg of extended release parasiticidal agents for a delivery period of at least 120 days.

Johnson in view of Runkel discloses a method and apparatus for the controlled release of a subcutaneous implant in cattle, except for the immediate release pharmaceutical composition comprising from about 25-125 mg and an extended release pharmaceutical composition comprising from about 50-175 mg, of said parasiticidal agent. Wallace teaches that it is known to use a dosage of ivermectin in the range of 0.0004 to 2.0 mg/kg of animal body weight, as set forth in paragraphs beginning at column 5, lines 20-57, to provide an effective dosage for treatment of fecue toxicosis in grazing animals. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the controlled release implant for cattle apparatus as taught by Johnson in view of Runkel with an immediate release pharmaceutical composition comprising from about 25-125 mg and an extended release pharmaceutical composition comprising from about 50-175 mg, of said parasiticidal agent as taught by Wallace, since such a modification would provide the controlled release implant for cattle apparatus with an immediate release pharmaceutical composition comprising from about 25-125 mg and an extended release pharmaceutical composition comprising from about 50-175 mg, of said parasiticidal agent for providing an effective dosage for treatment of fecue toxicosis in grazing animals.

Claims 25 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. in view of Runkel et al. in further view of Wallace.

Johnson et al. in view of Runkel et al. discloses the claimed invention except for the extended release delivery period of 120 days. Wallace teaches that it is known to use an extended release delivery period of 120 days, as set forth in paragraphs beginning at column 5, lines 3 – 57, to provide an effective dosage for treatment of fecue toxicosis in grazing animals. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus for the controlled release of a subcutaneous implant in cattle as taught by Johnson et al. in view of Runkel et al with an extended release delivery period is of 120 days as taught by Wallace, since such a modification would provide the apparatus for the controlled release of a subcutaneous implant in cattle with an extended release delivery period of 120 days for providing an effective dosage for treatment of fecue toxicosis in grazing animals.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER